

EXHIBIT 4

**RFA that asks for admission that NECC
violated the FDA's compliance guide**

RFA in this Sub-Category

29

REQUEST FOR ADMISSION NO. 29:

Prior to September 18, 2012, NECC violated the FDA Compliance Policy Guidance on Compounding⁵ in the following ways:

- a. NECC failed to operate in conformance with applicable state law regulating the practice of pharmacy.
- b. NECC compounded drug products that were commercially available in the marketplace or that were essentially copies of commercially-available, FDA-approved drug products.
- c. NECC used commercial-scale manufacturing or testing equipment when compounding drug products.

RESPONSE TO REQUEST FOR ADMISSION NO. 29:

Plaintiffs object to this RFA because the Request does not identify any specific provisions of the compliance policy which are alleged to be violated. Plaintiffs further object to this RFA because it is vague and unduly burdensome in that the Request is unlimited time and taken literally would require Plaintiffs to investigate events occurring as early as the foundation of NECC. Plaintiffs further object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

⁵ A copy of the Compliance Policy Guidance on Compounding in effect until December 2013 is attached as Exhibit B.